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HEALTH SCIENCE FUNDING, LLC Plaintiff vs THE UNITED STATES FOOD & DRUG ADMINISTRATION and Stephen Ostroff, Acting Commissioner of the FDA	UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY Civil Action # 15-cv-_____-CCC-MF **VERIFIED COMPLAINT**

Plaintiff Health Science Funding LLC, by its undersigned attorneys, as and for its Complaint in this matter, avers and alleges:

NATURE OF THE ACTION

1. Plaintiff makes a Medical Food for patients with lupus. Defendant The U.S. Food & Drug Administration (FDA) threatened to take baseless enforcement action against Plaintiff for marketing its product. Plaintiff accordingly asked this Court for a Declaratory Judgment that Plaintiff's product fully complies with the relevant Federal statute. *See Health Sci. Funding LLC v. Food & Drug Admin*., 13-cv-03663-CCC-MF (D.N.J. 2013) CM/ECF #1, 6, 7. In response, Defendant tried to evade judicial scrutiny by moving to dismiss. *See id*. at CM/ECF #10, 11.

This Court reviewed Plaintiff's motion for an injunction and Defendant's cross-motion to dismiss. On Oct. 31, 2013, this Court held an off-record conference with the parties. *See id*. at CM/ECF #17. At that conference, this Court indicated that should it make a ruling on the record, it would deny Defendant's motion to dismiss and, finding Plaintiff enjoyed a likelihood of success on the merits, grant Plaintiff's motion for a preliminary injunction. With that guidance, Defendant agreed to leave Plaintiff alone. Plaintiff reciprocated by staying its request for a Declaratory Judgment. This Court effected that agreement and closed the case. *See id*. at CM/ECF #19. For the next year and a half, the parties honored their bargain.

2. Last month, however, FDA inspectors Michael Klapal and Tonia Bernard of FDA's Parsippany, NJ District Office visited Plaintiff. They advise that Defendant now disavows its prior agreement and intends to seize Plaintiff's product.

3. Defendant having reneged on its agreement to leave Plaintiff alone, Plaintiff reluctantly asks the Court to use its limited resources to re-visit this case and issue the Declaratory Judgment that the parties' prior agreement was intended to obviate.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1346 (jurisdiction where the United States is a defendant).

5. The Plaintiff's requested relief is authorized under Fed. R. Civ. P. 65(a) (preliminary injunction), 28 U.S.C. § 2201 (declaratory relief) and 28 U.S.C. § 2202 (further relief).

6. Venue is properly vested in this Court under 28 U.S.C. § 1391(e)(3) because the Plaintiff resides in this District and no real property is involved in this action.

THE PARTIES

7. **Plaintiff**: Health Science Funding, LLC is a New Jersey limited liability company with its principle place of business in Morristown, NJ.

8. **Defendants**: The United States Food and Drug Administration (FDA) is part of the United States Department of Health and Human Services (HHS), an executive branch agency. Stephen Ostroff (named in his official capacity only) is the Acting Commissioner of the FDA.

FACTUAL BACKGROUND

9. DHEA is widely sold as a dietary supplement; it is available at *e.g.*, Wal*Mart, General Nutrition Center and amazon.com. *See* M. Pohl, *Declaration* (July 20, 2015) at Exhibit 1 (hereinafter, "Dec.Ex.1") and Exhibit 5 ("Dec.Ex.5").

10. For many consumers, DHEA dietary supplements are a waste of money. DHEA is secreted by the adrenal cortex, *see* Dec.Ex.2, and excess DHEA is simply excreted in the urine, *see* Dec.Ex.3 at 220 Table IV. Thus, DHEA, while not harmful, may not provide much benefit to many consumers.

11. DHEA is extremely valuable, however, for a particular group of people: women with systemic lupus erythematosus. While DHEA occurs naturally in humans, Female lupus patients have below normal levels of DHEA. *See* Dec.Ex.4 at 244 Fig. 1. This is apparently because lupus destroys the adrenal cortex, the gland which normally secretes it and because prednisone, a drug commonly used to treat lupus, degrades it. Taking the proper amount of DHEA restores lupus patients' DHEA level to the same level seen in healthy women. This simple change has a dramatic effect on health: it cuts patients' risk of breast cancer in half and reduces the risk of death from any cause ***by a stunning 80%***: a far greater benefit than many drugs achieve. *See* Dec.Ex.12 pg. 86-87.

12. DHEA has for decades been widely available as a dietary supplement. *See* Dec.Ex.1, Dex.Ex.5, Dec.Ex. 13 pg. 9 § 6 (discussing dietary supplement use as early as 1995). One could fairly ask why in the world lupus patients do not take DHEA dietary supplements.

13. First, DHEA dietary supplements have unreliable purity. *See* Dec.Ex.8, 14. Indeed, concern over unreliable quality has prompted several physicians to expressly advise patients to avoid DHEA dietary supplements. For example, THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION "recommends that people not take DHEA on their own":

> [Professor John Renner, M.D.] "recommends that people not take DHEA on their own. Recalling the impurities in tryptophan … led to a

> number of deaths and hundreds of cases of eosinopilia-myalgia syndrome, Renner notes that there is still no governmental regulation of the potency and purity of so-called nutritional supplements."

See Dec.Ex.15 pg. 1367 col. 3.

14. Further, without physician guidance, lupus patients may not understand DHEA's benefit, nor know how much of it to take, nor how often to take it, nor when to stop taking it (*e.g.*, if pregnant), nor what side effects to expect. Further, health insurance plans generally refuse to cover dietary supplements.

15. To address these needs, Plaintiff developed a pharmaceutically-pure DHEA product for sale not as a dietary supplement, but as a "Medical Food," *e.g.*, a dietary supplement available only under physician supervision, to address a specific medical condition (rather than general health / well-being). *See* 21 U.S.C. § 360ee(b)(3). Plaintiff took a commonly-available dietary supplement and made it safer by requiring reliable purity and physician supervision.

16. Plaintiff's product meets each element of the statutory definition of a "Medical Food". The statute says:

> "The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

See 21 U.S.C. § 360ee(b)(3). A "Medical Food" must thus meet several statutory elements. It must be consumed <u>orally</u> (enterally). It must be used under <u>physician</u>

supervision. It must be intended for a particular disease or condition, not simply for general health and well-being. And, the physician must make a medical evaluation to confirm that the patient in fact has distinctive nutritional requirements for it.[1]

17. Plaintiff's product fulfills each statutory element. The product is formulated to be consumed orally. *See* Dec.Ex.17 at § 2.1. The product is restricted for use under the supervision of a physician. *See id.* at § 1. The product is intended to manage a specific condition (systemic lupus erythematosus). *Id*. Many lupus patients have a distinctive nutritional requirement for DHEA because they have depressed blood levels of DHEA. *See* Dec.Ex.4 at 244 Fig. 1. The physician must make a medical evaluation to establish that the patient in fact has a distinctive nutritional requirement for DHEA. *See* Dec.Ex.17 at § 1. Plaintiff's product thus meets each and every legal element of the statutory definition of Medical Food. Plaintiff's product is thus a Medical Food as a matter of law.

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[1] Products which qualify as Medical Food are exempt from health claim labeling requirements, *see* 21 U.S.C. § 343(r)(1), (r)(5)(A); 21 C.F.R. § 101.14(f)(2), and are exempt from "Nutrient content" (e.g., serving size, calorie count) labeling, *see* 21 USC § 343(q)(1). While "medical," however, a Medical Food remains a food, and thus must comply with food-purity standards. Also, the label must contain a statement of identity (the common name of the product) (21 CFR 101.3), the net quantity of contents (21 CFR 101.105), the name and place of business of the manufacturer (21 CFR 101.5), and a complete list of ingredients (21 CFR 101.4).

18. Plaintiff asked FDA to vet Plaintiff's product. *See* Dec.Ex.18. FDA responded that it had "serious questions and concerns" with the label. *See* Dec.Ex.19. FDA did not, however, say what those allegedly "serious" concerns were. *Id*.

19. Plaintiff thus repeatedly asked FDA to identify its alleged concerns in writing. *See* Dec.Ex. 20, 21. FDA refused to do so. Rather, it responded via voice mail. *See* Dec.Ex.22. FDA acknowledged that the scientific literature shows DHEA helps lupus patients. *Id*. FDA, however, argued that "efficacy alone does not qualify a product to be marketed as a medical food". *Id*. FDA said it has two concerns regarding Plaintiff's product.

20. First, FDA noted that products freely available to consumers (*e.g.*, DHEA dietary supplements) are not "automatically" Medical Foods under the statute. *Id.*; Dec.Ex.23 at M. Pohl, email (Jan. 24, 2013). While this statement may be correct, it is not legally relevant. The question at hand is not whether all dietary supplements in the abstract "automatically" meet the statutory definition of Medical Food, but whether Plaintiff's particular product in fact does so.

21. Second, FDA advised that it is "not aware of any distinctive nutritional requirements" for lupus. *See id.* FDA's ignorance of lupus patients' requirement for DHEA, however, is not relevant as a matter of law. This is because the statute

requires that the "distinctive nutritional requirement" be established not by FDA, but by "medical evaluation" - *i.e.*, by the patient's physician. The statute says:

> "The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, <u>are established by medical evaluation</u>."

See 21 U.S.C. § 360ee(b)(3) (underlining mine). FDA does not (and cannot) make patient medical evaluations; doctors do. And patient medical evaluations are confidential medical records. FDA thus does not (and cannot) require patients or doctors to submit them to FDA for review. FDA ignorance of patients' medical evaluations is not merely understandable, but in fact required because privacy law forbids FDA from obtaining those evaluations. FDA's ignorance, however, is not legally relevant because the statute expressly requires the evaluation be made by the physician, not the FDA. *Id*.

22. To resolve FDA's two concerns, Plaintiff attended an in-person meeting with FDA. *See* Dec.Ex.23. At that meeting, FDA reiterated its two concerns: dietary supplements are not "automatically" Medical Foods, and FDA is not aware of any "distinct nutritional requirement" for DHEA in lupus patients. Further, FDA threatened enforcement action. FDA noted (correctly) that it can seize mislabeled product, FDA alleged that it had in fact recently seized another manufacturer's mislabeled product, and FDA threatened to seize Plaintiff's product

as allegedly not complying with 21 U.S.C. § 360ee(b)(3). FDA also demanded "immediate remedial action," but failed to say what remedial action could possibly be needed for a product which meets every element of the statute.

23. FDA's seizure threat was credible in light of FDA's numerous *Warning Letters* making similar threats against other medical food manufacturers. *See* Dec.Ex.24. Troublingly, FDA's various *Warning Letters* to other manufacturers also show that FDA arbitrarily and frequently takes positions contrary to the statute, and indeed contrary to FDA's own Regulations.

24. Perhaps more troublingly, FDA's *Warning Letters* appear specifically designed to produce an *in terrorem* effect, and appear specifically designed to frustrate judicial review. FDA's *Warning Letters* uniformly threaten product seizure *within 15 days*. *See* Dec.Ex.24. Fifteen days is hardly adequate time to provide a Federal Court adequate time to comfortably docket, review and rule on a dispute. Given FDA's threat of product seizure, a threat credible in light of FDA's pattern of enforcement against other manufacturers, *see* Dec.Ex.24, Plaintiff accordingly asked this Court for a Declaratory Judgment confirming that Plaintiff's product meets every element of the statutory definition of Medical Food. *See Health Sci. Funding LLC v. Food & Drug Administration*, 13-cv-03663-CCC-MF (D.N.J. 2013) CM/ECF #1.

PROCEDURAL BACKGROUND

25. Plaintiff asked this Court for a Declaratory Judgment confirming that Plaintiff's product label conforms to the statutory definition of Medical Food articulated in 21 U.S.C. § 360ee(b)(3). *See Health Sci. Funding LLC v. Food & Drug Administration*, 13-cv-03663-CCC-MF (D.N.J. 2013) CM/ECF #1. Plaintiff also asked for a Preliminary Injunction barring FDA enforcement action during litigation. *Id*. at CM/ECF #6, 7. In response, Defendant moved to dismiss. *Id*. at CM/ECF #10, 11.

26. This Court reviewed Plaintiff's motion for an injunction and Defendant's cross-motion to dismiss. On Oct. 31, 2013, the Court held an off-record conference with the parties. *See id*. at CM/ECF #17. At that conference, this Court indicated that should it make a ruling on the record, it would deny Defendant's motion to dismiss and, finding Plaintiff enjoyed a likelihood of success on the merits, grant Plaintiff's motion for a preliminary injunction. With that guidance, Defendant agreed to leave Plaintiff alone. Plaintiff reciprocated by staying its request for a Declaratory Judgment. This Court effected that agreement and closed the case. *See id*. at CM/ECF #19. For the next year and a half, the parties honored their bargain.

27. Last month (Friday June 19th, 2015, 9:05am) however, FDA inspectors Michael Klapal and Tonia Bernard of FDA's Parsippany, NJ District Office visited

Plaintiff. They advise that Defendant disavows its prior agreement and intends to seize Plaintiff's product.

28. On June 20th, Plaintiff accordingly asked this Court to review the situation. *See* Dec.Ex. 27. The Court generously agreed to do so. (Generous because the prior case was marked closed, so the Court did not have time budgeted to work on that closed file, but agreed to do so anyway.)

29. On July 15, 2015 at 10:30 a.m., the Court held a conference. Defendant assured the Court that there was no live controversy. Rather, Defendant represented to the Court that FDA would be sending a letter expressly confirming that no one at FDA headquarters had threatened enforcement action. Assured by FDA counsel that FDA inspector Klapal and Bernards' seizure threat was unauthorized, Plaintiff and the Court agreed there appeared to be no live controversy.

30. After the conference was concluded, FDA in fact delivered its promised letter to Plaintiff. FDA's letter, however, said nearly opposite what FDA had represented to this Court. *See* Dec.Ex. 28. Rather than confirm that FDA's seizure threat was the unauthorized excess of overly-enthusiastic junior employees, the letter accuses (without explaining why) Plaintiff's product of being illegitimate. Further, while FDA's letter confirms that FDA headquarters staff in Maryland did not travel to Plaintiff's New Jersey office to make their seizure threat, FDA's letter

tacitly confirms that FDA headquarters authorized FDA's Acting District Director in FDA's Parsippany NJ office to do so. Frustratingly, while FDA wrote its letter on July 2nd, FDA withheld it from the Court for two weeks, preventing the Court from reviewing it before its July 15th conference.

31. When Plaintiff received FDA's letter, Plaintiff promptly forwarded it to the Court. *See* Dec.Ex. 29. On July 16, 2015, the Court held a second conference to discuss the matter. The Court appeared frustrated by the fact that FDA's letter appeared to contradict FDA's prior representation to the Court that there was no live controversy. The Court constructively suggested that FDA Plaintiff in advance of any enforcement action, to enable Plaintiff to seek judicial review if warranted. FDA flatly refused. The Court thus agreed that Plaintiff could file the instant action.

32. Defendant having reneged on its agreement to leave Plaintiff's product alone, Plaintiff reluctantly asks the Court to use its limited resources to re-visit this case and issue the Declaratory Judgment that the parties' Oct. 2013 agreement was intended to obviate.

COUNT I - THE COURT SHOULD ISSUE A DECLARATORY JUDGMENT THAT PLAINTIFF'S PRODUCT COMPLIES WITH THE STATUTORY DEFINITION OF MEDICAL FOOD

33. Plaintiff respectfully asks the Court to issue a declaratory judgment under 28 USC § 2201(a) that Plaintiff's labeling meets the statutory definition of Medical Food in 21 U.S.C. § 360ee(b)(3).

34. Declaratory judgment avails to resolve questions of law on relatively undisputed facts. *See* Fed. R. Civ. P. Rule 57 at Advisory Comm. notes. For example, the Court may use a Declaratory Judgment to construe a statute. *Id*.

35. The instant case involves a straightforward issue of statutory construction. The Federal Food Drug & Cosmetic Act defines "Medical Food":

> "The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

See 21 U.S.C. § 360ee(b)(3). Thus, any dietary supplement which is used under physician supervision, formulated to be consumed orally, is intended for a particular disease or condition, and which requires the physician to make a medical evaluation to confirm that the patient in fact has distinctive nutritional requirements is, as a matter of law, a Medical Food.

36. In the instant case, Plaintiff's product meets each and every one of the statute's elements. *See* Dec.Ex.17, *see supra* ¶¶ 16-17. As a matter of law, Plaintiff's product thus meets the statutory definition of Medical Food. *See* 21 U.S.C. § 360ee(b)(3).

37. Plaintiff respectfully asks the Court to issue a Declaratory Judgment confirming that Plaintiff's product meets the statutory definition of Medical Food.

38. FDA argues that it knows of no "distinctive nutritional requirement" for DHEA in lupus patients. Dec.Ex.22; Dec.Ex.23 at M. Pohl, email (Jan. 24, 2013). FDA's alleged ignorance, however, is legally immaterial because the statute says that requirement must be established by physicians, not by FDA. *See* 21 U.S.C. § 360ee(b)(3). The statute articulates procedure for physicians to do so (a medical evaluation) and a standard for that procedure (based on scientific principles). *Id*. Indeed, the statute does not even mention the FDA. *Id*. Thus, the plain language of the statute gives physicians, not the FDA, authority to make this evaluation.

39. The FDA apparently recognizes that it lacks authority to make this evaluation because it has steadfastly refused to put in writing its ostensible legal position. *See* Dec.Ex. 19, Dec.Ex.22; Dec.Ex.23 at M. Pohl, email (Jan. 24, 2013); Dec.Ex.28.

COUNT II - THE COURT SHOULD PRESERVE THE *STATUS QUO* AND ENJOIN FDA FROM TAKING ENFORCEMENT ACTION AGAINST PLAINTIFF'S PRODUCT

40. Until this Court rules on the merits, Plaintiff respectfully asks the Court to enjoin FDA from taking any enforcement action against Plaintiff's product.

41. Preliminary injunctions are intended to maintain the *status quo* pending a final adjudication. *See Opticians Ass'n of Am. v. Indep. Opticians of Am*., 920 F.2d 187, 197 (3d Cir. 1990). In the instant case, Plaintiff has been marketing its product since 2013. *See* Dec.Ex.16. Since then, FDA has repeatedly threatened enforcement action, but has also repeatedly refused to put its alleged "serious"

questions into writing. To preserve this *status quo*, the Court should enjoin FDA from taking enforcement action until this Court issues a ruling on the merits. *See Opticians Ass'n of Am.*

42. To issue a preliminary injunction, a court must consider four factors: 1) Whether the moving party demonstrates a "reasonable probability" of success on the merits, 2) Whether the moving party may be irreparably injured in preliminary relief is denied, 3) Whether granting preliminary relief will result in even greater harm to the non-moving party, and 4) Whether preliminary relief will be in the public interest. *See e.g., Novartis Consumer Health v. Johnson & Johnson – Merck Consumer Pharmaceuticals Co.*, 290 F.3d 580, 586 (3rd Cir. 2002). In this case, all four factors support granting an injunction.

Plaintiff Demonstrates A "Reasonable Probability" Of Success On The Merits

43. Plaintiff demonstrates a reasonable probability of success on the merits. Plaintiff's product meets each and every statutory element. *See* Dec.Ex.17. This Court has already informally concluded this. Indeed, even FDA tacitly concedes this because FDA flatly refuses to explain in writing its alleged concerns. *See* Dec.Ex.19, 22, 23, 28. FDA's years-long refusal to justify its threats shows that FDA itself believes Plaintiff will win on the merits.

Plaintiff Will Be Irreparably Injured If Preliminary Relief Is Denied

44. Plaintiff will be irreparably harmed if preliminary relief is denied. The Court of Appeals for the Third Circuit instructs that for a preliminary injunction analysis, "irreparable harm" includes potential loss of future sales and market share. *See Novartis Consumer Health v. Johnson & Johnson – Merck Consumer Pharmaceuticals Co*., 290 F.3d 580, 596 (3rd Cir. 2002). In the instant case, FDA's threat of seizure chills Plaintiff's willingness to distribute its product, and chills physicians' willingness to prescribe it. This potential loss of future sales and market share is "irreparable harm". *See Novartis Consumer Health* at 596.

45. FDA may argue that Plaintiff's alleged future loss is merely speculative. Speculative injury, however, suffices for relief. The Third Circuit instructs that a manufacturer must merely establish that it has a "reasonable basis" for believing that it is "likely to suffer injury". *Id*. at 595. A manufacturer "need not come forward with specific evidence that the challenged claims actually resulted in some definite loss of sales". *Id*. In the instant case, FDA's threat of enforcement action provides a reasonable basis to believe Plaintiff will suffer lower sales and market share.

Preliminary Relief Will Not Harm The FDA

46. Preliminary relief will not harm the FDA. Indeed, FDA tacitly concedes this. While verbally threatening Plaintiff with enforcement action, FDA has pointedly refrained from taking any. FDA's long period of inaction shows that

FDA recognizes that neither FDA nor the public has been harmed by, nor will not be harmed by, the status quo.

47. One of the goals of preliminary injunctions being "to maintain the *status quo*," *see Opticians Ass'n of Am. v. Indep. Opticians of Am.*, 920 F.2d 187, 197 (3d Cir. 1990). Here, preliminary relief merely preserves the *status quo* created by the FDA's own inaction.

Preliminary Relief Advances
A Critical Public Interest

48. The most cogent reason to preserve the status quo, however, involves neither Plaintiff nor FDA, but lupus patients.

49. Every day, lupus kills almost 5 people in the U.S. *See* Dec.Ex.6, 7. Most victims are women, many are young. *Id*. And lupus is not an easy death: kidney failure, cancer, routine infection and suicide. *Id*.

50. The active ingredient in Plaintiff's product does not cure lupus, but it helps. It reduces the risk of auto-immune flares. Dec.Ex.10 at Fig. 1 and Table 2; Dec.Ex.11 at Table 3. It reduces the risk of breast cancer. Dec.Ex.12 at pg. 98. It reduces the risk of death from any cause ***by a stunning 80%***. Dec.Ex.12 at pg. 86-87. Thus, of the nearly five women lupus kills in the U.S. every day, Plaintiff's product could save the lives of 3 or 4. *See id*.

51. Further, DHEA is known to be safe. It has been commonly available in the U.S. for decades, and is already widely sold as a dietary supplement. Dec.Ex.1, 6. FDA's own internal reviews indicate that it is safe. Dec.Ex. 13, 25.

52. Enjoining arbitrary and caprecious FDA enforcement action advances the public interest because it enables vulnerable patients to better access a safe, potentially life-saving product, and enables physicians to better care for these vulnerable patients.

Saving The Lives Of Four Women A Day Is
Not A Bad Day's Work For Your Honor

53. This case thus gives Your Honor a somewhat rare opportunity: how often can you go home in the evening and tell your family that you saved four innocent women's lives today? How often can you say that you helped save four women's lives today, and another four tomorrow, and another four every tomorrow, for years? This case gives this Court the opportunity to create quite a legacy.

The Court Must Give Defendants At Least Five Days
Notice Of A Preliminary Injunction Hearing

54. To grant a preliminary injunction, the Court must give Defendants at least five days advance notice of the preliminary injunction hearing. *See* Hon. M. Denlow, *The Motion for a Preliminary Injunction*, 22 REV. LIT. 495, 505-06 (2003), *citing* Fed. R. Civ. P. Rule 6(d).

55. The Court may also consolidate the preliminary injunction hearing with the trial on the merits. *See* Fed. R. Civ. P. 65(a)(2). To consolidate, the Court must

provide notice to the parties adequate to enable the parties to make of record their evidence. *See Anderson v. Davila*, 125 F.3d 148, 157 (3rd Cir. 1997). Plaintiff respectfully suggests that the instant case – with undisputed facts and a simple statute - appears amenable to such an expedited resolution.

PRAYER FOR RELIEF

56. FDA alleges it has "serious" questions, yet flatly refuses to reduce those questions to writing. Plaintiff thus asks this Court to issue a Declaratory Judgment holding that Plaintiff's product meets the statutory definition of Medical Food.

57. To preserve the *status quo*, Plaintiff asks this Court to enjoin FDA from taking enforcement action against Plaintiff's product. Plaintiff accordingly respectfully asks this Court to:

A. **Issue an Order to Show Cause** under Local Civil Rule 65.1 requiring FDA to show cause why a preliminary injunction should not issue enjoining FDA from taking enforcement action against Plaintiff and its product; and

B. **Temporarily Enjoin** FDA from commencing enforcement action against Plaintiff and its product until the Court issues a Declaratory Judgment; and

C. **Declare** in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act) that Plaintiff's product complies with the statutory definition of "Medical Food" under 21 U.S.C. § 360ee(b)(3); and

D. **Permanently Enjoin** FDA from taking enforcement action against Plaintiff's Product for so long as its labeling complies with the statutory definition of "Medical Food" under 21 U.S.C. § 360ee(b)(3).

E. **Order such other relief** and the Court deems necessary and proper to prevent FDA from taking arbitrary and capricious enforcement action against Plaintiff, its agents or its product.

Respectfully submitted on behalf of Plaintiff
Health Science Funding LLC by its attorneys,
PHARMACEUTICAL PATENT ATTORNEYS LLC

_/s Mark Pohl_____
Mark Pohl, Esq. (JP-4457)

VERIFICATION

I, J. Mark Pohl, attorney for Health Science Funding LLC, have read the foregoing Verified Complaint. Based on my personal knowledge, I hereby certify that on information and belief after a reasonable investigation, (a) the statements set forth in this Complaint are true and accurate, and (b) the matter in controversy is not subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

__/s Mark Pohl_____
J. Mark Pohl
Dated as of July 20, 2015